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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/697,741	10/30/2003	Mei-Chiao Wu	11702-003006	9062
26161	7590	11/04/2005	EXAMINER	
FISH & RICHARDSON PC P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022			LILLING, HERBERT J	
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 11/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/697,741	<b>Applicant(s)</b> WU ET AL.	
	<b>Examiner</b> HERBERT J. LILLING	<b>Art Unit</b> 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 October 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 33-35 and 41-59 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 33 and 41-46 is/are allowed.
- 6) ☒ Claim(s) 34 and 47-59 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

Art Unit: 1651

1. Receipt is acknowledged of the amendment filed October 14, 2005.
2. Claims 33-35 and 41-59 are now pending in this application.

Claims 1-31 and 36-40 have been cancelled.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

A. Claims 34-35 and 47-59 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention which is **“containing fungus-produced hydrophobic compounds of a molecular weight less than or equal to 1kDa”**.

Applicant is kindly requested to show support in the instant specification for the claimed subject matter that is commensurate in scope with the above language.

B. Claims 34-35 and new claims 47-59 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while there is a possibility that the product by processes of the examples in the instant specification may be patentable, but the instant specification does not reasonably provide enablement for the instantly claimed product claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and practice the invention commensurate in scope with these claims.

Art Unit: 1651

Applicant is **required to submit the structure of the products per se** in the claimed pharmaceutical composition or sufficient physical properties which includes nmr, ir or any other figure or data commensurate in scope with the claimed language **"containing fungus-produced hydrophobic compounds."** There is no way to do a proper search and examination for the claimed subject matter drawn to these unknown products.

Claims 34-35 and new claims 47-59 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for fraction(s) as noted by the specification examples, does not reasonably provide enablement for the claimed subject matter without specificity of the process conditions to obtain the pharmacologically active hydrophobic **compounds**. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and practice the invention commensurate in scope with these claims.

The language of the claims must make it clear what subject matter the claims encompass to adequately delineate their "metes and bounds". The courts have also indicated that before claimed subject matter can properly be compared to the prior art, it is essential to know what the claims do in fact cover. See, e.g., the following decisions: **In re Steele**, 305 F 2d. 859, 134 USPQ 292 (CCPA 1962); **In re Moore** 439 F 2d. 1232, 169 USPQ 236 (CCPA 1969); **In re Merat**, 519 F 2d. 1390, 186 USPQ 471 (CCPA 1975).

C. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 34-35 and new claims 47-59 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 34-35 and 47-59 are rendered vague and indefinite by the claimed processes because the processes do not adequately delineate its metes and bounds. The active **hydrophobic compounds** are products-by-process defined by the processes of its preparation but the claims lack sufficient information or limitations to define the compound(s) that is 9ARE) isolated. Such products-by-processes claims are intended to define products, which are otherwise difficult to define and/or distinguish from the prior art except, by the process of making. Since any given biological source contains a multiple of possible active fractions as indicated, each with its own particular properties, the nature of the resulting fraction will depend on the conditions to obtain the fractions to obtain the "fungus-produced hydrophobic compounds of a molecular weight less" commensurate in scope with the claimed language. Applicant will be required to submit a sufficient number of properties for the claimed "hydrophobic compounds" e.g., the specific molecular weight of the fraction, spectra properties, and or/and the specific separation processes. Accordingly, without the recitation of all these critical limitations as set forth above, the claims do not adequately define the instant

Art Unit: 1651

invention. Without the above information a proper search and examination cannot be properly commensurate in scope with the made for the claimed subject matter unless Applicant provides the necessary information as to the structure of the each and every component for the claimed hydrophobic compounds.

5. **Claims 33 and 41-46 are allowed.**

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Examiner Lilling whose telephone number is 571-272-0918 and Fax Number is (703) 872-9306** or SPE Michael Wityshyn whose telephone number is 571-272-0926. Examiner can be reached Monday-Thursday from about 5:30 A.M. to about 3:00 P.M. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Information regarding the status of an application may be obtained from the Patent Application information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://portal.uspto.gov/external/portal/pair>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

H.J.Lilling: HJL

(571) 272-0918

Art Unit **1651**

November 01, 2005



Dr. Herbert J. Lilling  
Primary Examiner  
Group 1600 Art Unit 1651